

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

UNITED STATES OF AMERICA EX REL.
CRYSTAL DERRICK,

Plaintiff-Relator,

v.

ROCHE DIAGNOSTICS CORP.; ROCHE
DIABETES CARE, INC.; ROCHE HOLDINGS
AG; HUMANA, INC.; AND HUMANA
PHARMACY, INC.,

Defendants.

Case No. 14-cv-04601

Judge Bucklo
Magistrate Judge Gilbert

**MEMORANDUM OF LAW IN SUPPORT OF ROCHE DIAGNOSTICS
CORPORATION'S AND ROCHE DIABETES CARE, INC.'S MOTION TO DISMISS**

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Defendants Roche Diagnostics Corporation (“Roche Diagnostics”) and Roche Diabetes Care, Inc. (“Roche Diabetes Care”) (collectively, “Roche”) respectfully submit this Memorandum of Law in support of their Motion to Dismiss Plaintiff-Relator Crystal Derrick’s (“Relator”) Second Amended Complaint (“SAC”). Dkt. 29.

INTRODUCTION

This case is the unavailing attempt by a disgruntled former Roche employee to criminalize benign business conduct. The conduct at issue was the renegotiation in 2013 and 2014 of two contracts concerning blood glucose testing products and related supplies that Roche provided to members of private health plans and Medicare Advantage (“MA”) plans operated by Defendant Humana.^{1/} Both contracts were in writing and were openly negotiated at arm’s-length. Under one contract, Roche paid rebates to Humana in exchange for Roche products having a favored position in Humana’s approved product list (also known as its “formulary” or “Preferred Formulary Position”). The other contract offered discounts on Roche’s products sold through Humana’s mail order pharmacy. At the same time, Roche and Humana concurrently settled a disputed liability under the rebate agreement.

The SAC represents the third attempt by Relator to plead actionable claims. She now alleges that all of the Defendants’ routine business dealings were crimes under the Anti-Kickback Statute (“AKS”), 42 U.S.C. § § 1320a-7b(b), thereby giving rise to liability under the False Claims Act (“FCA”), 31 U.S.C. § 3729. She further blames Roche’s termination of her employment on supposed “retaliation” for purportedly raising concerns about the Humana contracts with her supervisors.

^{1/} Defendants Humana, Inc. and Humana Pharmacy, Inc. are collectively referred to as “Humana.”

Relator's assertion that there were illegal "kickbacks" in violation of the AKS is the only basis for her contention that any "false claim" was submitted to the government. She does not allege that this purported scheme cost the government a penny more, resulted in unnecessary utilization, involved Roche products not actually provided or that were defective, or that any patient was harmed in any way. Instead, she rests her FCA claim on a 2010 amendment to the AKS, which provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g). Thus, in order for these actual sales of medically-necessary products to give rise to "false claims," Relator must be correct that Defendants' above-board, open, and routine commercial dealings could constitute a criminal kickback scheme.

Relator's theory is incorrect as a matter of logic and the law. The very contracts on which she premises her AKS claims fall within a regulatory "safe harbor" established by the Office of Inspector General ("OIG"). The OIG is the agency within the Department of Health and Human Services charged with investigating AKS and other Medicare fraud cases, interpreting the AKS, and issuing these safe harbors that specify conduct that is not covered by the AKS. The specific safe harbor at issue here permits and encourages MA plans to enter into precisely the types of written incentive or discount agreements that Relator attacks in the SAC. Under the OIG managed care safe harbor, contracts like the ones between Roche and Humana are expressly permitted. Given the Defendants' open negotiation and execution of written agreements that satisfy the safe harbor, Relator does not and cannot allege facts sufficient to meet the heightened degree of scienter, or consciousness of wrongdoing, that the AKS requires. In addition, simultaneous settlement of a disputed liability and entry into legitimate discount and rebate agreements does not satisfy Relator's burden under the AKS to allege the payment of

improper remuneration in exchange for referrals. Insofar as Relator's FCA claims rest entirely on the alleged existence of a purported kickback, the failure to plead actionable AKS violations requires that those claims be dismissed.

Finally, Relator's FCA anti-retaliation claim also fails because she cannot show that she engaged in the requisite "protected conduct" needed to secure relief under the FCA's employment discrimination provision. Accordingly, for the reasons stated herein, the Court should dismiss the SAC with prejudice.

RELEVANT FACTUAL BACKGROUND^{2/}

On June 18, 2014, Relator filed her Complaint (Dkt. No. 1) under seal. Her First Amended Complaint followed on June 22, 2015 (Dkt. No. 7). On May 12, 2017, the United States declined to intervene in this *qui tam* action (Dkt. No. 20), and the Court unsealed Relator's complaints. Dkt. No. 7. Thereafter, on June 30, 2017, Relator filed her SAC, which sets forth allegations concerning (i) the resolution of a contract dispute between Roche Diagnostics^{3/} and Humana, which "is one of the largest [MA] providers in the country"; (ii) parallel negotiations between Roche and Humana for Roche to pay rebates for preferred access to the Humana formularies and to sell its diabetes supplies through Humana's mail order pharmacy; and (iii)

^{2/} As it must, and only for the purposes of this Rule 12 motion, Roche assumes all well-pleaded factual allegations in the SAC are true. However, because the SAC refers to and is premised on the provisions of agreements between Roche and Humana, those agreements are incorporated into the pleadings in this case. "Documents that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in plaintiff's complaint and are central to her claim." *Venture Assocs. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir. 1993) (citing cases). "The purpose of this exception is to prevent parties from surviving a motion to dismiss by artful pleading or by failing to attach relevant documents." *DeJohn v. TV Corp. Int'l*, 245 F. Supp. 2d 913, 916 n.2 (N.D. Ill. 2003) (quoting *188 LLC v. Trinity Industries, Inc.*, 300 F.3d 730, 735 (7th Cir. 2002)). Here, Relator's claims rest on the terms of agreements that she alleges implement the purported illegal kickback scheme. See SAC, ¶ 71. Accordingly, in deciding this motion, the Court may consider and evaluate the legal significance of those agreements. Copies of the agreements will be filed separately under seal or with redactions to omit confidential commercial information not relevant to this Motion. To the extent that allegations in the SAC are contradicted by the terms of those agreements, the terms and contents of those agreements control. See *Graue Mill Dev. Corp. v. Capital Int'l Ltd.*, 927 F.2d 988, 991 (7th Cir. 1991).

^{3/} Defendant Roche Diabetes Care, Inc. was incorporated in November 2015 – i.e., at a time period not covered by Relator's allegations. SAC, ¶ 6.

Roche's termination of Relator's employment, purportedly due to Relator "reporting a fraud." SAC, ¶¶ 3, 8, 48.

Under MA, Medicare enters into contracts with MA organizations ("MAOs"), such as Humana, to provide beneficiaries with services and supplies covered under Medicare Parts A and B. SAC, ¶ 26. In turn, MAOs contract with "first tier" entities, such as Roche, to provide such services and supplies. *Id.* at ¶36. The SAC identifies two related contracts between the parties. The first is a 2009 Retail Rebate Agreement,^{4/} renegotiated without interruption, effective January 1, 2014, as the 2014 Retail Rebate Agreement^{5/} (collectively, the "Retail Rebate Agreements"). *See id.* ¶¶ 51, 69; *see also* Exs. A, B. The second is a 2011 Mail Order Agreement^{6/} with Humana Pharmacy Solutions, Inc. ("HPS," previously known as RightSource), which was terminated in June 2013, but was renegotiated (through an agreement effective as of December 20, 2013) as the 2013 Mail Order Agreement^{7/} (collectively, the "Mail Order Agreements"). Exs. C, D; *see* SAC, ¶¶ 48, 50, 69.

MAOs are not paid on a fee-for-service basis, but instead are paid by Medicare on a fixed ("capitated" or "at risk") per-member, per-month basis. Although adjustments are made that will pay MAOs more for members who are more costly, *see* SAC, ¶ 32, MAOs are "at risk" that the cost of services provided to MA plan members may exceed the Medicare capitated payments,

^{4/} The Roche Diagnostics Corporation and Humana Pharmacy Solutions Commercial and Medicare Advantage Rebate Agreement, effective August 5, 2009, as amended October 15, 2012 (the "2009 Retail Rebate Agreement") (Exhibit A).

^{5/} The Roche Diagnostics Corporation Rebate Agreement (Retail), by and Roche Diagnostics Corporation and Humana Pharmacy Solutions, Inc. effective January 1, 2014 (the "2014 Retail Rebate Agreement") (Exhibit B).

^{6/} The Roche Diagnostics Corporation and Humana Pharmacy Solutions Medical Benefit Rebate Agreement, by and between Roche Diagnostics Corporation and Humana Pharmacy, Inc. effective January 4, 2011, as amended February 1, 2012 (the "2011 Mail Order Agreement") (Exhibit C).

^{7/} The Roche Diagnostics Corporation Purchase and Rebate Agreement (Mail Order) by and between Roche Diagnostics Corporation and Humana Pharmacy, Inc. effective December 20, 2013 (the "2013 Mail Order Agreement") (Exhibit D).

creating strong incentives to control utilization and costs. *See id.* ¶ 27. One way to do so is through contractual arrangements such as the Retail Rebate Agreements. As an MAO, Humana pays for blood glucose testing supplies purchased by its members at retail pharmacies. The Retail Rebate Agreements provide Humana significant discounts from Roche in the form of rebates conditioned on Humana charging a higher copayment (a “Copayment Differential”) to members who purchase competing products on Humana’s limited product formulary. *Id.* ¶¶ 45, 51. In contrast, under the Mail Order Agreements, HPS purchases Roche’s products for sale to Humana members directly through Humana’s own mail order pharmacy. *See id.* ¶ 48. Here, Humana controls costs by encouraging its members (typically through lower copayments) to purchase Roche’s products and related supplies through HPS, with costs savings achieved through significant volume purchasing discounts from Roche. *See id.* ¶ 43; Exs. C, D.^{8/}

In the spring of 2013, Relator claims that she “discovered” Humana failed to implement the Copayment Differential, meaning that Roche had paid rebates that were not owed (“Rebate Overpayment”). SAC, ¶ 51. Relator contends that she “was advised at that time that the total amount of the overpayment was \$45 million.” *Id.* ¶ 55. In a July 8, 2013 call with Humana, however, Roche proposed that Humana pay \$27.6 million to resolve the Rebate Overpayment. *Id.* ¶¶ 59, 60. In a subsequent call, Humana countered that it would pay no more than \$20 million. *Id.* ¶ 64. Over the course of the next several months the parties negotiated a settlement to resolve the Rebate Overpayment. *Id.* ¶¶ 64, 70. Pursuant to the Settlement Agreement, the final amount was \$22.5 million.^{9/}

^{8/} The Mail Order Agreements also provide for Roche to pay rebates based on specified criteria, but these provisions are not relevant to this case.

^{9/} The Settlement Agreement and Mutual Release by and between Roche Diagnostics Corporation and Humana Pharmacy Solutions, Inc. dated December 1, 2013 (the “Settlement Agreement”) (Exhibit E). Although the
(Continued on next page)

In parallel, the parties renegotiated the Retail Rebate and the Mail Order Agreements, culminating with the 2014 Retail Rebate Agreement and 2013 Mail Order Agreement. *Id.*; Exs. B, D. Relator claims that Roche, in violation of the AKS, accepted a discount on the Rebate Overpayment in exchange for renegotiation of the Retail Rebate and Mail Order Agreements. SAC, ¶ 71. She alleges that the “debt forgiveness” settlement was given “in exchange for access to Humana’s Right Source book of business, as well as continued access to the Medicare and Commercial formularies.” *See id.* ¶¶ 64, 71, 73. But at the same time, Relator takes no issue with the contracts themselves.

Relator claims that Roche terminated her employment because she “question[ed] [] the lawfulness of Defendants’ conduct involving its efforts to gain access to Humana’s formularies.” *Id.* ¶ 107. Relator avers that she “repeatedly raised” and “expressed concerns” to Roche “corporate management” that the Rebate Overpayment negotiations and resulting 2014 Retail Rebate Agreement and 2013 Mail Order Agreement “would violate the AKS.” *Id.* ¶¶ 3, 67, 79. Relator claims the reason given for her December 2013 termination – that she improperly sent Roche confidential information to an outside party – was a pretext to mask her illicit termination for raising concerns about the Rebate Overpayment and Humana negotiations. *Id.* ¶¶ 80-91.

ARGUMENT

I. The SAC Must Be Dismissed for Failure to Plead an Actionable AKS Violation.

Where, as here, a relator’s FCA claims are based entirely on alleged violations of the AKS, *see* SAC, ¶¶ 22-23, proof of an AKS violation is “a necessary precondition for Relator’s purported claims under the False Claims Act.” *Klaczak v. Consol. Med. Transp.*, 458 F. Supp.

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SAC incorrectly states that the payment “did not exceed \$11 million,” *see* SAC, ¶ 70, the terms and contents of the Settlement Agreement control. *See Graue Mill Dev. Corp.*, 927 F.2d at 991 (discussed above at note 2).

2d 622, 662 n. 33 (N.D. Ill. 2006); *United States v. Omnicare, Inc.*, No. 07 C 05777, 2013 U.S. Dist. LEXIS 102543, at *27-28 (N.D. Ill. July 23, 2013) (same). But stripped down to its essence, Relator only makes the unsupported assertion that it is a crime under the AKS for Roche and Humana to settle a disputed rebate liability, and then await resolution of that dispute to renew legitimate discount and rebate agreements.

The Court should find no AKS violation for two compelling reasons. One, Congress and the OIG, through its “safe harbor” process, have said that the AKS does not apply to written MAO agreements where Medicare pays Humana on a capitated basis. Two, Relator fails to plead the elements of an AKS offense, most importantly completely failing to allege “willfulness,” i.e. that the Parties knew their conduct was illegal.

A. As a matter of law, the OIG managed care safe harbor dictates it is not an AKS violation when Humana and Roche entered into written agreements where Humana is paid under the MA program on a capitated basis.

The AKS proscribes the knowing and willful paying or receiving “remuneration” in return for the referral of patients or recommending the ordering of goods or services that are reimbursed under a Federal health program. 42 U.S.C. § 1320a-7b(b)(1)-(2). Congress has also said that conduct that falls within specific exceptions, such as for managed care, or a safe harbor issued by the OIG, are not offenses under the AKS. 42 U.S.C. § 1320a-7b(b)(3)(E)-(F).

Among other things, safe harbors clarify that certain arrangements in managed care plans do not fall within the ambit of the AKS. As early as the original 1991 safe harbors, the OIG took the formal position that arrangements involving managed care plans paid by Medicare on a capitated or “risk contract” basis have fundamental attributes that have little to do with the harms resulting from typical kickback schemes. “[Health maintenance organizations] and other health plans under contract with [Medicare] or a State [Medicaid] agency have built-in incentives to control unnecessary utilization, or have their utilization and costs monitored by [Medicare] or the

State [Medicaid] agency.” 56 Fed. Reg. 35952, 35961 (July 29, 1991). As a result, the OIG concluded, “We recognize that HMOs and CMPs paid in accordance with a risk contract with [Medicare] or a State health care program deserve special attention.” *Id.* at 35979. This policy led the OIG to grant favorable safe harbor treatment for discounts offered to risk contract health plans. *See* 42 C.F.R. § 1001.952(h)(1)(i) (stating that section 1876 health plans need “not report the discount except as otherwise may be required under the risk contract”). In 1996 Congress ultimately enacted the managed care exception, which the OIG implemented in 1999, both granting even broader protections for written agreements for health plans paid on a capitated basis. The SAC expressly relies upon and cites written agreements between Roche and Humana that meet all of the safe harbor requirements. Because the very agreements on which Relator bases her claims are not AKS offenses, her FCA claims fail as a matter of law and must be dismissed.

1. Defendants’ written agreements comply with the intent of Congress’s AKS managed care exception.

The AKS contains a managed care statutory exception, which provides that “any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a *written agreement* between the organization and the individual or entity if the organization is an eligible organization under section 1876 [42 USCS § 1395mm]” will not be considered remuneration under the AKS. 42 U.S.C. § 1320a-7b(b)(3)(F) (emphasis added). The express words of the statute evince Congressional intent to confer broad discretion to Medicare managed care plans to enter into written discount agreements, so long as there are no side oral agreements for additional remuneration to induce referrals.

The original statutory managed care exception was enacted before Congress created the MA program, *see* Social Security Act (“SSA”) § 1854, codified at 42 U.S.C. § 1395w–24, and thus incorporates an outdated statutory reference to a now-terminated Medicare managed care program under SSA § 1876. However, OIG’s 1999 implementing regulation includes Medicare Part C (MA) plans – such as the Humana plans in this action – within the regulatory definition of “eligible managed care organizations” that are permitted under the managed care safe harbor. *See* 42 C.F.R. § 1001.952(t)(2)(ii)(B) (“Eligible managed care organization means . . . (B) Any Medicare Part C health plan that receives a capitated payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by CMS under section 1854 of the Act.”)

As the SAC alleges, the written 2013 Mail Order Agreement and 2014 Retail Rebate Agreement, which Relator claims to be illegal, concern MA plans. *See generally* SAC; 2013 Mail Order Agreement (Ex. D), ¶ 1 (Definition of “Eligible Plan”); 2014 Retail Rebate Agreement (Ex. B), ¶ 1 (Definition of “Eligible Plan”), Ex. A-1 (pricing for MA Eligible Plans). When considering these provisions in light of the statutory managed care exception, the Court should only conclude that the Defendants have met the exception’s only requirement to put their agreements in writing, and that they have met the intent of the exception.

2. The SAC pleads all the necessary elements to establish Defendants’ compliance with the OIG’s managed care safe harbor

The contracts cited, but not attached, in the SAC fall squarely within the current OIG managed care safe harbor. Specifically, the regulation states that the term “remuneration,” as used in the AKS, “does not include any payment between” an “eligible managed care organization and any first tier contractor” (“FTC”) under an agreement that satisfies the following three requirements:

- (i) The agreement “is set out in writing, and signed by both parties;” “[s]pecifies the items and services covered by the agreement;” “is for a period of at least one year;” and “specifies that the [FTC] cannot claim payment” from a Federal health care program except in certain circumstances; 42 C.F.R. § 1001.952(t)(1)(i)(A);
- (ii) “[N]either party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than the business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis;” 42 C.F.R. § 1001.952(t)(1)(i)(B); and
- (iii) “[N]either party to the agreement shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.” 42 C.F.R. § 1001.952(t)(1)(i)(C).

With respect to the first safe harbor requirement, both the 2014 Retail Rebate Agreement (Ex. B) and 2013 Mail Order Agreement (Ex. D) are written, signed agreements for at least one year. *See* Ex. B, ¶ 8.1 (“Term”); Ex. D, ¶ 10.1 (“Term”). This safe harbor provision also requires that the FTC (here, Roche) “cannot claim payment in any form directly or indirectly from a Federal health care program for items or services covered under the agreement,” with certain exceptions that are inapplicable. 42 C.F.R. § 1001.952(t)(1)(i)(A)(4). The SAC alleges only that Humana, not Roche, seeks Medicare payments. *See* SAC, ¶¶ 72, 77. Relator makes no claim that Roche seeks Medicare payments, nor could it, insofar as payments under Medicare Part C go directly to the MAO (Humana), and the two contracts accordingly state that Roche’s products are paid by Humana. Ex. B, ¶ 3 (“Rebate Terms”), Ex. D, ¶ 2.2 (“Price”). As to the second requirement (neither party may have any deals outside the agreements to induce business on fee-for-service or cost basis), the SAC alleges only that Humana is paid on a capitated basis. SAC, ¶ 77. Finally, “[n]either party to the agreement[s] shifts the financial burden of the agreement[s] to the extent that increased payments are claimed from a Federal health care program.” The allegations in the SAC also demonstrate compliance with this final requirement

for the reasons stated above: the SAC alleges Humana is paid on a capitated basis, and the agreements demonstrate that the payment source for Roche is through Humana.

The Settlement Agreement is protected as well under the safe harbor. It is an adjustment to the rebate amounts owed under the 2009 Retail Rebate Agreement, and therefore is appropriately analyzed with that agreement. As the 2009 Retail Rebate Agreement has been in effect since 2009, subject to the October 15, 2012 amendment, it has been in effect for over one year, with the Settlement Agreement not amending the length of term of the underlying agreement. For the same reasons discussed *supra* with respect to the 2014 Retail Rebate Agreement (Ex. B) and 2013 Mail Order Agreement (Ex. D), the Settlement Agreement and 2009 Retail Rebate Agreement meet all other requirements of this safe harbor. *See, e.g.* Ex. A, ¶ 3.1 (Products), Ex-C (Pricing and Rebate schedules) (showing Roche is paid by Humana).

Thus, as pleaded in the SAC, Relator's claims rest entirely on agreements that fall squarely within the regulatory managed care safe harbor. As a result, the Court can and should dismiss Relator's FCA claims by reason of her inability to plead an actionable AKS violation.

B. In addition to falling within the managed care safe harbor, the conduct alleged does not violate the AKS, thus requiring dismissal of Counts I-III.

A second compelling reason the Court should dismiss the SAC is because Relator fails to allege an AKS violation. To prove an AKS violation, Relator must show that Roche: (1) knowingly and willfully, (2) offered or paid, (3) remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person, (4) to induce or in return for, (5) the referral of an individual or recommending the ordering of any item or service, (6) for which payment may be made in whole or in part under a Federal health care program. *See* 42 U.S.C. § 1320a-7b(b)(1), (2). Because Relator fails to plead all of these essential elements, the FCA claims resting on those alleged AKS violations must be dismissed.

1. Relator has not alleged Defendants acted with criminal intent

The Relator's third attempt to articulate an AKS violation excises the express criminal intent requirement embodied in the "willfulness" scienter element of the AKS; instead she seeks to apply the relaxed civil standard of "knowing" misconduct. *See* SAC, ¶ 17. But, the AKS expressly requires that Defendants "knowingly" and "willfully" engaged in criminal misconduct, and to proceed under the FCA, there must be a finding of a "violation" of the AKS. 42 U.S.C. § 1320a-7b(b)(1), (b)(2), (g).

"A person acts willfully if he acts intentionally and purposely and with the intent to do something that the law forbids." *Klaczak*, 458 F. Supp. 2d at 675 (internal citation omitted). "The use of the term 'willfully' in conjunction with the term 'knowingly'" in the AKS demonstrates that "'willfully' must mean 'more than acting intentionally.'" *U.S. v. Williams*, 218 F. Supp. 3d 730, 736 (N.D. Ill. 2016) (quoting *United States v. Wheeler*, 540 F.3d 683, 690 (7th Cir. 2008)). While a defendant need not specifically know of and intend to violate the AKS, to act "willfully" a defendant must nonetheless "know that his conduct was in some way unlawful." *Williams*, 218 F. Supp. 3d at 736 (quoting *Wheeler*, 540 F.3d. at 690).^{10/}

Here, the SAC's allegations that Defendants openly entered into the challenged written agreements, without any allegations evidencing consciousness of illegality or wrongdoing, do not satisfy Relator's heightened burden to plead scienter under the AKS. In *United States ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396, 2015 U.S. Dist. LEXIS 117900, at *81-83 (S.D. Tex. Sep. 3, 2015), *aff'd*, 663 F. App'x 368 (5th Cir. 2016), the court found that evidence the

^{10/} A majority of courts ruling on the question have interpreted the AKS's willfulness element as requiring proof the defendant knew his conduct was illegal. *See United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) (upholding jury instruction, "[w]illfully means to do something purposely, with the intent to violate the law, to do something purposely that law forbids."); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Starks*, 157 F.3d 833, 837-38 (11th Cir. 1998); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1399-1400 (9th Cir. 1995).

defendant knew of the existence of a contract renewal discussions while at the same time settling a contract dispute was insufficient to establish scienter under the AKS.^{11/} Accordingly, because, the SAC is bereft of any factual allegations demonstrating that Roche acted with sufficient *scienter* to violate the AKS, Counts I-III of the SAC should be dismissed.

2. Allegations that Roche and Humana conditioned ongoing contracts on the resolution of the rebate dispute show common, benign business conduct and not remuneration in exchange for referrals.

Relator's unsupported theory – that negotiations between Roche and Humana concerning the Rebate Overpayment constitute remuneration in violation of the AKS – is devoid of logic. Stripped of its rhetoric, the SAC merely alleges the Defendants negotiated a contract dispute settlement, and agreed to condition completion of ongoing contract renegotiations on the resolution of this dispute. It is hard to imagine more benign business conduct, and as a matter of law such conduct does not rise to the level of remuneration in exchange for referrals or recommending items and services under the AKS.

Relator's theory rests on the bare allegation that Roche agreed to compromise a dispute “in exchange for new and continued access to Humana's formularies.” SAC, ¶ 71. Citing to two cases (*Ruscher*, 2015 U.S. Dist. LEXIS 117900; and *United States ex rel. Fontanive v. Caris Life Scis., Inc.*, No. 3:10-CV-02237-P, 2013 U.S. Dist. LEXIS 188016 (N.D. Tex. Oct. 23, 2013)), Relator contends that a “company's failure to collect money that is owed to it by an entity from

^{11/} This is not a question of Relator's failure to use the magic word “willful” as well as “knowing.” Such a “formulaic recitation of the elements of a cause of action,” even if alleged, would fail to satisfy Relator's pleading burden. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555); see *Mohammed v. Sidecar Techs., Inc.*, No. 16 C 2538, 2016 U.S. Dist. LEXIS 156090, at *4 (N.D. Ill. Nov. 10, 2016) (a court deciding a Rule 12 motion to dismiss FCA claims “‘need[] not accept as true legal conclusions, or threadbare recitals of the elements of a cause of action, supported by mere conclusory statements.’”) (quoting *Alam v. Miller Brewing Co.*, 709 F.3d 662, 665-66 (7th Cir. 2013)). The SAC does not allege concealment, furtive actions, or undisclosed conduct or anything that bespeaks of consciousness of illegality or wrongdoing. *Cf. Starks*, 157 F.3d at 836-40 (arrangements to make alleged kickback payments in remote parking lots evidenced defendants' scienter).

which the company intends to induce such reimbursement . . . is considered remuneration under the AKS.” SAC ¶ 21. Relator contends that the difference between what Roche believed it was owed and the amount for which it settled with Humana was remuneration. *Id.* ¶¶ 59-71.

Although *Ruscher* did state that “forgiveness of debt owed for services rendered *can* constitute ‘remuneration’ for the purposes of the AKS,” 2015 U.S. Dist. LEXIS 117900, at *37, (emphasis added), that principle does not permit Relator to equate an agreement to compromise a disputed liability with illegal remuneration in return for referrals. In *Ruscher*, the relator claimed that Omnicare violated the AKS by forgiving debt owed by skilled nursing facilities (“SNFs”). The court ultimately held that there was “no evidence of an intent to induce referrals . . . rather than the settlement of a legitimate dispute,” because, as is true here, the defendant in *Ruscher*, was “understandably – interested in a quick resolution to the dispute [with a SNF] in order to preserve the parties’ business relationship.” *Id.* at *43.

The SAC also fails to allege that remuneration was paid in return for referrals. To rise to the level of inducement in violation of the AKS, the offer or payment must be made with “intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.” *Hanlester Network*, 51 F.3d at 1398 (internal quotations and citations omitted). The SAC does not identify any physician who received anything of value as a result of the 2013 Mail Order Agreements or 2014 Retail Rebate Agreements, and only alleges that “Roche’s reduction of Humana’s [alleged] obligation to repay Roche in exchange for new and continued access to Humana’s formularies violates the AKS’s prohibition against providing and accepting remuneration” SAC, ¶ 71. Alleging that the Defendants compromised a dispute and renegotiated ongoing contracts conditioned on the resolution of the dispute fall far short of articulating a kickback scheme to exchange remuneration for referrals.

The second case cited by Relator, *Fontanive*, does not support her theory either. Most importantly, *Fontanive* has nothing to do with compromising a disputed contract amount. Rather, that case involved allegations that the defendant laboratory waived billing hospital clients **known** amounts for services clearly rendered to induce a continued referral stream. 2013 U.S. Dist. LEXIS 188016, at *39-42. The court found that the alleged failure to bill the undisputed amount adequately pleaded remuneration under the AKS. *See id.*

Critically, the SAC alleges nothing of the sort. Unlike *Fontanive*, Relator fails to allege that there was any undisputed amount due to Roche from Humana. Relator does not allege that the \$27.6 million figure purportedly communicated to Relator was either the actual amount due or a reduction from a larger undisputed amount owed. *See* SAC, ¶ 59. And, most significantly, Relator never alleges that **Humana** knew, understood or even acknowledged that it owed **any** specific Rebate amount to Roche. Rather than alleging payment of remuneration, what Relator actually alleges are facts consistent with the compromise of a disputed liability with the parties agreeing to condition ongoing contractual relations with its resolution. *See* SAC, ¶¶ 47, 50-71. Defendants' above-board, arm's-length resolution of legitimate business issues is precisely the type of agreement that *Ruscher* held not to be remuneration for purposes of the AKS. *See Ruscher*, 2015 U.S. Dist. LEXIS 117900, at *64 (no "bad purpose" shown when "Omnicare employees were negotiating over A/R in the shadow of contract negotiations") (citation omitted). Accordingly, because Relator did not and cannot allege essential elements of an AKS violation, the Relator's FCA claims should be dismissed.

3. Because Relator has failed to allege an AKS violation, Counts I, II and III all must fail.

Because Relator has not adequately plead an AKS violation, Counts I-III of the SAC must be dismissed. *See United States ex rel. Kalec v. NuWave Monitoring, LLC*, 84 F. Supp. 3d

793, 800 (N.D. Ill. 2015) (In the absence of an adequately-pled unlawful scheme to defraud the government, there can be no claim for conspiracy under the FCA); *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1049-51 (N.D. Ill. 2002) (dismissing FCA claim for failure to establish underlying AKS violation).

II. The Court Should Dismiss Relator’s Retaliation Claim (Count IV) Because Relator Does Not And Cannot Meet Her Burden To Prove That She Engaged In Protected Conduct.

Count IV alleges that Roche terminated Relator’s employment in violation of the FCA’s anti-retaliation provision, 31 U.S.C. § 3730(h), because of certain “concerns” that she raised with various Roche employees as to the purported “illegality of the negotiations” between Roche and Humana. SAC, ¶¶ 67, 79. Specifically, Relator asserts that she “eventually became concerned about Roche’s planned response to her discovery of the [rebate] overpayment,” and that she “repeatedly expressed concerns” to Roche personnel contending that “the resulting transaction would violate the AKS.” *Id.* Relator’s retaliation claim, however, cannot survive Rule 12 scrutiny unless the SAC plausibly alleges that Relator engaged in conduct protected by the FCA (“protected conduct”). *Fanslow v. Chicago Mfg. Ctr., Inc.*, 384 F.3d 469, 479 (7th Cir. 2004). Because Relator does not do so, Count IV should be dismissed.

Under § 3730(h)(1) Relator’s alleged report of concerns about FCA violations will be protected conduct only if (1) Relator has a good faith belief that there was a violation; and (2) “a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government” *United States ex rel. Uhlig v. Fluor Corp.*, 839 F.3d 628, 635 (7th Cir. 2016) (citation and internal quotations omitted). To satisfy that “second, ‘objective’ prong,” *see id.*, “the employee must undertake the protected conduct with the actual **and reasonable** belief that the employer is committing fraud against the government.” *United*

States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 715 (7th Cir. 2014) (emphasis added) (internal quotations and citations omitted).

Relator's retaliation claim fails for at least two reasons. First, she cannot satisfy the objectivity test for the existence of protected conduct. For the myriad of reasons discussed *supra*, it is evident that Relator did not plausibly assert a FCA violation. *Singer v. Progressive Care, SC*, 202 F. Supp. 3d 815, 828 (N.D. Ill. 2016) ("Because [relator] has failed to state a claim with respect to his claims under § 3729(a)(1)(A) and § 3729(a)(1)(B), his FCA retaliation claim fails as well") (citing *United States ex rel. McGinnis v. OSF Healthcare Sys.*, No. 11-cv-1392, 2014 U.S. Dist. LEXIS 12600, at *28 (C.D. Ill. Jan. 31, 2014) (same)). Because Relator's asserted "protected conduct" cannot satisfy the objectivity prong, Relator should not be allowed to prosecute a costly and baseless retaliation claim. *See id.*

Second, Relator cannot simply point to the AKS and assert conclusory allegations to survive a Rule 12 motion to dismiss. *Brandon v. Anesthesia & Pain Mgmt. Assocs., Ltd.*, 277 F.3d 936, 944-45 (7th Cir. 2002) (finding that simply alerting employer of non-compliance or illegality does not satisfy the protected conduct element). Broad, vague, generalized warnings about wrongdoing fail to state a plausible FCA anti-retaliation claim; Relator must provide the employer with specific, factual allegations of fraud being committed against the government. *United States ex rel. Bragg v. SCR Med. Transp., Inc.*, No. 07-CV-2328, 2012 U.S. Dist. LEXIS 81644, at *10 (N.D. Ill. June 8, 2012) ("[Relator's] objection to [employer's] conduct alone is not sufficient to constitute protected activity.") (citation omitted); *Farmer v. Eagle Sys. & Servs.*, No. 5:14-CV-403, 2015 U.S. Dist. LEXIS 2492, at *8 (E.D.N.C. Jan. 9, 2015) ("to constitute protected activity, a whistle-blower's report must specifically allege fraud on the government,

and not just general misconduct.”). Because Relator does not allege that she provided any such specific information to Roche, the Court should dismiss Count IV for that reason as well.

CONCLUSION

For the above-stated reasons, Roche respectfully submits that this Court should dismiss the SAC as to Roche in its entirety.

ROCHE DIAGNOSTICS CORPORATION
ROCHE DIABETES CARE, INC.

By their attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that, on October 2, 2017, a true and correct copy of the foregoing has been served electronically on all parties of record via the court's CM/ECF system.

/s/ Thomas S. Crane

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